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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

NOVO NORDISK A/S and NOVO  
NORDISK INC.,

Plaintiffs,

v.

ENDURE HEALTH AND  
WELLNESS LLC,

Defendant.

Civil Action No. 2:24-cv-10391

**COMPLAINT**

Plaintiffs Novo Nordisk A/S (“NNAS”) , with a principal place of business at Novo Alle 1, 2880 Bagsvaerd, Denmark, and Novo Nordisk Inc. (“NNI”) , with a principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536, (collectively, “Plaintiffs” or “Novo Nordisk”) , by and through their undersigned attorneys, for their complaint for false advertising and unfair and deceptive trade practices seeking injunctive, monetary, and other relief against Defendant Endure Health and Wellness LLC (“Defendant”), with a principal place of business at 111 S Orange Ave Suite 37, South Orange, New Jersey 07079, hereby allege as

follows, on actual knowledge with respect to themselves and their own acts, and on information and belief as to all other matters.

### **INTRODUCTION**

1. Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases like diabetes and obesity.
2. The development of semaglutide is an example of Novo Nordisk's commitment to innovation for people living with chronic diseases. Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk's three prescription-only medicines approved by the Food and Drug Administration ("FDA"): Ozempic<sup>®</sup> (semaglutide) injection and Rybelsus<sup>®</sup> (semaglutide) tablets for adults with type 2 diabetes and Wegovy<sup>®</sup> (semaglutide) injection for chronic weight management.
3. Novo Nordisk is the only company in the United States with FDA-approved medicines containing semaglutide.
4. Novo Nordisk is also the only company authorized to identify its medicines containing semaglutide using the trademarks Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup>.
5. The FDA has not approved any generic versions of semaglutide medicines. To the contrary, the FDA has sent warning letters to companies that have claimed that their unapproved drug products have the "[s]ame active ingredient as Ozempic, Rybelsus, and Wegovy," noting that Ozempic and Wegovy are currently the only "two injectable semaglutide products FDA-approved for the U.S. market."<sup>1</sup>

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<sup>1</sup> FDA – Warning Letter to Ozempen.com, MARCS-CMS 684435 — JUNE 24, 2024, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ozempencom-684435-06242024>.

6. This action is brought pursuant to the Lanham Act, 15 U.S.C. §§ 1051 et seq., related state laws, and the common law arising out of Defendant's acts of false advertising and unfair and deceptive trade practices in violation of Plaintiffs' rights in their Wegovy<sup>®</sup>, Ozempic<sup>®</sup>, and Rybelsus<sup>®</sup> marks.

7. Defendant markets and sells to patients compounded drug products that purport to contain semaglutide.

8. Even though such compounded drug products have not been evaluated by the FDA for their safety, effectiveness, or quality, Defendant falsely and misleadingly represents to patients that its products are FDA-approved or the same as, or equivalent to, Novo Nordisk's FDA-approved semaglutide medicines.

9. Defendant's conduct is likely to confuse and deceive patients into mistakenly believing that they are purchasing authentic Novo Nordisk medicines or medicines that have been evaluated by the FDA, studied in clinical trials, and deemed safe and effective.

### **THE PARTIES**

10. Plaintiff NNAS is a corporation organized and existing under the laws of the Kingdom of Denmark and has its principal place of business at Novo Alle 1, 2880 Bagsvaerd, Denmark.

11. Novo Nordisk developed the Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines.

12. NNAS has granted to Plaintiff NNI exclusive rights to market, advertise, promote, offer for sale, and sell Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines in the United States.

13. NNI is a corporation organized and existing under the laws of Delaware and has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

14. NNI promotes, offers, and sells Novo Nordisk's Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines throughout the United States, including in this District.

15. Defendant Endure Health And Wellness LLC is a New Jersey limited liability company with a business address at 111 S Orange Ave Suite 37, South Orange, New Jersey 07079.

16. Defendant sells and promotes compounded drug products that purport to contain semaglutide, but that have not been approved by the FDA (“Unapproved Compounded Drugs”).

17. Defendant falsely claims, or otherwise misleadingly suggests, that its Unapproved Compounded Drugs are the same as or equivalent to Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines.

### **JURISDICTION AND VENUE**

18. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 15 U.S.C. § 1121 and 28 U.S.C. § 1338(a).

19. The Court has supplemental jurisdiction over the state and common law causes of action pleaded herein pursuant to 28 U.S.C. § 1338(b).

20. Defendant is subject to personal jurisdiction in this Court because Defendant is a New Jersey limited liability company and has a principal place of business in this District.

21. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant resides in this District, manufactures and sells its compounded drug products that purport to contain semaglutide in this District, and otherwise conducts business in this District.

### **NOVO NORDISK’S FDA-APPROVED SEMAGLUTIDE MEDICINES AND OZEMPIC<sup>®</sup>, WEGOVY<sup>®</sup>, AND RYBELSUS<sup>®</sup> TRADEMARKS**

22. Plaintiffs use the trademarks “Ozempic,” “Wegovy,” and “Rybelsus” to identify and promote the FDA-approved Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines. The Ozempic<sup>®</sup> and Wegovy<sup>®</sup> medicines are sold and marketed in the United States by NNAS’s indirect, wholly-owned subsidiary, NNI.

23. The Ozempic<sup>®</sup> medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise. The Ozempic<sup>®</sup> medicine also lowers the risk of major cardiovascular events such as stroke, heart attack, or death in adults with type 2 diabetes and known heart disease.

24. The Wegovy<sup>®</sup> medicine is indicated to reduce excess body weight and maintain weight reduction long term in adults and children aged  $\geq 12$  years with obesity, and some adults with overweight and weight-related medical problems, along with a reduced calorie diet and increased physical activity. The Wegovy<sup>®</sup> medicine is also indicated, with a reduced calorie diet and increased physical activity, to reduce the risk of major adverse cardiovascular events such as “cardiovascular” death, heart attack, or stroke in adults with known heart disease and with either obesity or overweight.

25. The Rybelsus<sup>®</sup> medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise.

26. The Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines have been extensively studied in clinical trials and are FDA-approved.

27. Each of the Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines has a unique safety and efficacy profile which is set forth in its respective product label.

28. The Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines are prescription-only medicines that should be prescribed only in direct consultation with, and under the supervision of, a licensed healthcare professional.

#### **DEFENDANT’S SALE OF UNAPPROVED COMPOUNDED DRUGS**

29. Novo Nordisk has not authorized Defendant to use its marks, has not provided Defendant with Novo Nordisk’s FDA-approved semaglutide medicines, and does not sell the

bulk semaglutide in Novo Nordisk's FDA-approved semaglutide medicines to any compounding pharmacies from which it may be sourcing its Unapproved Compounded Drugs.

30. Defendant markets and sells to patients Unapproved Compounded Drugs that purport to contain semaglutide and that are not approved by the FDA.

31. The FDA has not approved Defendant's Unapproved Compounded Drugs.

32. On information and belief, the Unapproved Compounded Drugs sold by Defendant are made by compounding pharmacies, which deliver them either directly to patients or to Defendant for administration or dispensing to patients.

33. The FDA defines compounding as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."<sup>2</sup>

34. According to the FDA, "[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients."<sup>3</sup>

35. The FDA has further stated that compounded drugs "do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks."<sup>4</sup>

36. As the FDA has explained, "[c]ompounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review

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<sup>2</sup> Human Drug Compounding, <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding>.

<sup>3</sup> Compounding Laws and Policies, <https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies>.

<sup>4</sup> Compounding and the FDA: Questions and Answers, <https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers>.

for safety, quality or effectiveness. Compounded drugs should only be used for patients whose medical needs cannot be met by an available FDA-approved drug.”<sup>5</sup>

37. The process used to produce most “semaglutide” used in compounding is fundamentally different from the process used to produce the semaglutide in Novo Nordisk’s FDA-approved medicines. Novo Nordisk manufactures the semaglutide in its medicines, pursuant to its FDA approval, in yeast cells under a closely controlled multistep process that uses recombinant DNA technology. Most compounded “semaglutide,” however, uses a “semaglutide” manufactured via chemical synthesis. The fundamental differences between these processes have resulted in new impurities, higher levels of known impurities, immunogenicity concerns, and potential stability issues in tested samples of compounded “semaglutide.”<sup>6</sup>

38. The FDA has received reports of adverse events, some requiring hospitalization, related to overdoses from dosing errors associated with compounded “semaglutide” products.<sup>7</sup> Based on data as of September 30, 2024, the FDA’s Adverse Event Reporting System (FAERS) database includes 619 cases of adverse events associated with compounded “semaglutide”—nearly triple the number of adverse events for *all* compounded drugs in 2022.<sup>8</sup> Of those 619 cases, the FDA classified 446 as “serious” adverse events, 144 as requiring hospitalization, and

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<sup>5</sup> FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, <https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded>.

<sup>6</sup> Morten Hach *et al*, Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-On GLP-1 Polypeptide Drugs, *Pharm. Res.*, (Oct. 8, 2024), *available at* <https://pubmed.ncbi.nlm.nih.gov/39379664/>.

<sup>7</sup> FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, <https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded>.

<sup>8</sup> FDA Adverse Event Reporting System (FAERS) Public Dashboard, <https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard> (last visited October 31, 2024).

twelve as involving deaths. In several instances, patients mistakenly administered five to 20 times more than the intended dose of compounded “semaglutide.”

39. The FDA has stated that the containers and packaging (including multidose vials and prefilled syringes) used by compounders, the varying product concentrations, and the instructions accompanying the compounded drug contribute to the potential medical errors.

40. A publication from the Journal of the American Pharmacists Association also highlighted errors where patients accidentally self-administered doses of compounded “semaglutide” up to ten times greater than the intended amount.<sup>9</sup>

41. FDA has issued guidance on its “Concerns with Unapproved GLP-1 Drugs Used for Weight Loss,” which provides that: (1) “compounded drugs are not FDA-approved”; (2) use of compounded drugs containing “semaglutide” “can be risky for patients, as unapproved versions do not undergo FDA’s review for safety, effectiveness and quality”; and (3) “FDA has received reports of adverse events related to compounded versions of semaglutide . . . . However, federal law does not require state-licensed pharmacies that are not outsourcing facilities to submit adverse events to FDA so it is likely that adverse events from compounded versions of these drugs are underreported.”<sup>10</sup>

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<sup>9</sup> Joseph E. Lambson et al, *Administration Errors of Compounded Semaglutide Reported to a Poison Control Center—Case Series*, 63 J. Am. Pharmacists Assc’n 5 (2023), available at [https://www.japha.org/article/S1544-3191\(23\)00231-5/abstract](https://www.japha.org/article/S1544-3191(23)00231-5/abstract).

<sup>10</sup> FDA’s Concerns with Unapproved GLP-1 Drugs Used for Weight Loss, <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss>.



**DEFENDANT’S FALSE ADVERTISING IN CONNECTION WITH ITS  
SALE OF UNAPPROVED COMPOUNDED DRUGS**

42. Despite the foregoing, Defendant falsely advertises its Unapproved Compounded Drugs by making statements that describe the Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines but that are false or misleading when in reference to Defendant’s Unapproved Compounded Drugs.

43. Defendant has claimed or implied that its Unapproved Compounded Drugs have been approved by the FDA or have been reviewed by the FDA for safety, effectiveness, and quality.

44. Defendant has claimed or implied that its Unapproved Compounded Drugs contain the same semaglutide that the FDA evaluated in the context of reviewing and approving Novo Nordisk’s new drug applications for the Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines.

45. Defendant has claimed or implied that its Unapproved Compounded Drugs are compounded or generic versions of Wegovy<sup>®</sup> and Ozempic<sup>®</sup>.

46. The claims in the preceding three paragraphs are false and misleading.

47. On information and belief, Defendant has engaged in these unlawful practices to attract customers and generate revenues and profits, including by passing off its Unapproved Compounded Drugs purporting to contain “semaglutide” as Ozempic<sup>®</sup> and Wegovy<sup>®</sup> or authorized variations of those medicines.

48. Novo Nordisk has no control over the nature, quality, or efficacy of the products sold by Defendant, including the Unapproved Compounded Drugs.

49. Defendant’s false advertising is reflected in the paragraphs that follow as well as **Exhibit A** hereto.

50. Defendant falsely claims on its website that its Unapproved Compounded Drugs have been approved by the FDA or have been subjected to clinical studies and trials.

Semaglutide is a medication that has been approved for the treatment of type 2 diabetes, but it has also shown promising results in weight loss. The medication belongs to a class of drugs called glucagon-like peptide-1 receptor agonists (GLP-1 RAs) that mimics the effects of a naturally occurring hormone called glucagon-like peptide-1 (GLP-1). GLP-1 helps to regulate blood sugar levels, suppresses the release of glucagon, a hormone that raises blood sugar levels and slows down the emptying of the stomach, which helps to reduce food intake and promote feelings of fullness.

Studies have shown that Semaglutide is highly effective at reducing body weight in patients with and without diabetes. In a study published in the New England Journal of Medicine in 2021, researchers found that patients with obesity who took Semaglutide lost an average of 15.3% of their body weight after 68 weeks of treatment. This is a significant weight loss compared to patients who were treated with a placebo, who lost an average of 2.6% of their body weight.

Another study published in the Lancet in 2018 looked at the effectiveness of Semaglutide in combination with a low-calorie diet and [exercise](#) in patients with obesity. The study found that patients who received Semaglutide lost an average of 13.8% of their body weight after 52 weeks of treatment, compared to 2.3% for patients who received a placebo.

51. Novo Nordisk's FDA-approved medicines are the only drugs containing semaglutide to have been publicly studied for weight loss in clinical trials.

52. On information and belief, no such data exists for Defendant's Unapproved Compounded Drugs.

53. Defendant also falsely indicates that its Unapproved Compounded Drugs are a generic version of the Ozempic® and Wegovy® medicines and that the latter are merely a "brand name" version of Defendant's Unapproved Compounded Drugs:

**Hair Loss and Weight Loss Medications**

Semaglutide and Tirzepatide, known by their brand names Ozempic, Wegovy, Mounjaro, and Zepbound, have been associated with reports of hair loss, particularly following rapid weight loss. However, it's important to note that hair loss is not considered a common or permanent side effect of these medications. Not everyone using Semaglutide or Tirzepatide will experience hair loss.

54. Defendant's characterization of Ozempic® and Wegovy® as the "brand names" of its Unapproved Compounded Drugs falsely indicates that Defendant's Unapproved Compounded Drugs are a generic version of the Ozempic® and Wegovy® medicines. A generic drug is one

that the FDA has found to meet the “same high standards of quality and manufacturing as the brand-name product.”<sup>11</sup> No generic form of Plaintiffs’ FDA-approved Ozempic<sup>®</sup> and Wegovy<sup>®</sup> medicines exists.

55. The FDA has not reviewed, let alone approved as a generic drug, Defendant’s Unapproved Compounded Drugs for safety, effectiveness, or quality. Defendant has no basis to claim that its Unapproved Compounded Drugs are a generic version of, or otherwise equivalent to, Novo Nordisk’s FDA-approved medicines.

56. Defendant also makes claims that falsely equate its Unapproved Compounded Drugs with Novo Nordisk’s FDA-approved medicines.

57. Defendant falsely and misleadingly represents to patients that its Unapproved Compounded Drugs contain the same active ingredient as, and are equivalent to, the Ozempic<sup>®</sup> and Wegovy<sup>®</sup> medicines:

### **Weight Loss Medications**

At Endure Health and Wellness, we specialize in optimizing your weight loss journey with a range of highly effective medications. Our comprehensive approach includes the use of Semaglutide (the active ingredient Ozempic, Wegovy, Rybelsus), Tirzepatide (the active ingredient in Mounjaro), and other weight loss and appetite control options to help you achieve your goals efficiently and safely.

**Semaglutide**, in particular, has emerged as our most popular medication for weight loss due to its exceptional results. With this medication, our patients have experienced a significant reduction in body weight, typically ranging from 15% to 18%. Its proven track record makes it a preferred choice for many individuals seeking successful weight loss outcomes.

All our medications are sourced from an FDA-Approved and Supervised Compounding Pharmacy to ensure the highest quality and safety. We take pride in mailing these medications directly to your door, making it convenient and hassle-free.

To embark on your weight loss journey, we invite you to contact us for a FREE initial weight loss consultation. Our team of experts will work closely with you to create a personalized plan tailored to your unique needs and aspirations. With our guidance and support, you can confidently take steps towards a healthier and happier you.

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<sup>11</sup> U.S. Food & Drug Administration – Generic Drugs: Questions & Answers (March 16, 2021) <https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers#:~:text=A%20generic%20drug%20is%20a,performance%20characteristics%2C%20and%20intended%20use.>

## Semaglutide for Weight Loss

### Semaglutide

- Active ingredients in Wegovy, Rybelsus, and Ozempic
- [Semaglutide](#) is in a class of medications called Glucagon-like peptide-1 (GLP-1) agonists, which mimic hormones that are involved in blood sugar control and appetite; it is a powerful appetite suppressant.
- [Semaglutide](#) also works by increasing the production of insulin and appears to enhance the growth of  $\beta$  cells in the pancreas, which are the sites of insulin production.
- [Semaglutide](#) was approved by the FDA in June 2021, for the management of adults with chronic obesity or overweight with at least one weight-related condition (such as high blood pressure, type 2 diabetes, or high cholesterol).
- [Semaglutide](#) is indicated for patients with a body mass index (BMI) of 27 or greater who have at least one weight-related ailment or in patients with a BMI of 30 or greater.
- In clinical studies the average individual lost 15(+) % of their body weight.
- **Side Effects:** Mild fatigue, intermittent nausea, constipation, and diarrhea. This is not a full list of possible side effects, but the most common we have gotten feedback on. Some can be prevented based on water intake and nutrition choices.
- You are **NOT** a good candidate for Semaglutide if you have any of the following: diabetic retinopathy, Type 1 diabetes, low blood sugar, decreased kidney function, pancreatitis, medullary thyroid cancer (or a family history of medullary thyroid carcinoma), multiple endocrine neoplasia type 2, pregnant or breastfeeding.

58. To the contrary, Novo Nordisk is not directly or indirectly supplying semaglutide to Defendant or any compounding pharmacies from which it may be sourcing its Unapproved Compounded Drugs.

59. On information and belief, Defendant has engaged in these unlawful practices to attract customers and generate revenues and profits.

60. Defendant's false and misleading statements and practices are likely to cause mistake and deception in the marketplace.

61. Defendant's false and misleading marketing is also likely to expose patients to unnecessary risks. Patients who mistakenly believe Defendant to be offering Novo Nordisk's FDA-approved medicines, or equivalent thereto, are unlikely to understand the unique risks

associated with, or the lack of clinical trials or testing establishing the safety and effectiveness of, Defendant's Unapproved Compounded Drugs.<sup>12</sup>

62. On information and belief, unless enjoined by this Court, Defendant will continue to falsely advertise its products as being equivalent to, or associated with Ozempic® and Wegovy®, all in violation of Plaintiffs' rights.

### **FIRST CAUSE OF ACTION**

#### **False and Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B)**

63. Plaintiffs reallege and incorporate each allegation in the preceding paragraphs of this Complaint as though fully set forth here.

64. Defendant's practices, as described in this Complaint, constitute unfair competition and false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

65. Defendant has violated the Lanham Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and qualities of Defendant's business practices and products, as set forth above.

66. Defendant has also engaged in other false or misleading advertising and promotion intended to assure patients that Defendant's practices are lawful when in fact they are not. On information and belief, Defendant provides patients who purchase Defendant's Unapproved Compounded Drugs (or patients whom Defendant is trying to persuade to purchase

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<sup>12</sup> See, e.g., Dozens Say They Lost Eyesight After Routine Surgery Using Compounded Pharmacy Drugs, WFAA, <https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097> (reporting mistaken belief of patient taking a compounded drug that "every pill you take, every shot you take is tested.").

its drugs) information that makes false or misleading statements, including those described herein and in the exhibit hereto.

67. The above-described acts of Defendant, if not enjoined by this Court, are likely to deceive members of the general public.

68. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs.

69. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

70. By reason of Defendant's acts as alleged above, Plaintiffs have suffered and will continue to suffer injuries, including injury to Plaintiffs' business reputation.

71. Because Plaintiffs' remedies at law are not adequate to compensate for all the injuries inflicted by Defendant, Plaintiffs are entitled to entry of preliminary and permanent injunctive relief requiring Defendant to cease its false and misleading advertising and promotion and unfair competitive practices.

72. Because the above-described acts of Defendant are willful, the Court should award disgorgement of Defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117 to Plaintiffs.

73. This case is exceptional, making Plaintiffs eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

## **SECOND CAUSE OF ACTION**

### **Unfair Competition in Violation of the Common Law**

74. Plaintiffs reallege and incorporate each allegation in in the preceding paragraphs of this Complaint as though fully set forth here.



75. The above-described acts of Defendant constitute common law unfair competition.

76. The above-described acts of Defendant unfairly and wrongfully exploit Plaintiffs' trademark, goodwill, and reputation.

77. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

78. Because Plaintiffs' remedies at law are not adequate to compensate for the injuries inflicted by Defendant, the Court should enter preliminary and permanent injunctive relief, in addition to awarding disgorgement of Defendant's profits and corrective advertising costs to Plaintiffs.

### **THIRD CAUSE OF ACTION**

#### **Unfair Competition in Violation of the New Jersey Fair Trade Act N.J.S.A § 56:4-1 *et seq.***

79. Plaintiffs reallege and incorporate each allegation in the preceding paragraphs of this Complaint as though fully set forth here.

80. The New Jersey Fair Trade Act, N.J.S.A § 56:4-1 *et seq.*, prohibits merchants from appropriating a name, brand, trade-mark, reputation, or goodwill of any maker in whose product such merchant, firm, or corporation deals.

81. Defendant has violated the New Jersey Fair Trade Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and/or qualities of Defendant's business practices and products, as set forth above.

82. Defendant has also engaged in other false or misleading advertising and promotion intended to assure patients that Defendant's practices are lawful when in fact they are not. On information and belief, Defendant provides patients who purchase Defendant's Unapproved Compounded Drugs (or patients whom Defendant is trying to persuade to purchase its drugs) information that makes false or misleading statements, including those described herein and in the exhibit hereto.

83. The above-described acts of Defendant, if not enjoined by this Court, are likely to deceive members of the general public.

84. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs.

85. The Court should enter preliminary and permanent injunctive relief, in addition to awarding disgorgement of Defendant's profits attributable to Defendant's statements to Plaintiffs.

### **REQUEST FOR RELIEF**

WHEREFORE, Plaintiffs request judgment against Defendant as follows:

1. That the Court enter a judgment against Defendant that Defendant has:
  - a. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a);
  - b. Engaged in unfair competition under the common law and in violation of the New Jersey Fair Trade Act, N.J.S.A. § 56:4-1 *et seq.*
2. That the Court find that each of the above acts was willful.
3. That the Court preliminarily and permanently enjoin and restrain Defendant and its agents, servants, employees, successors, and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with Defendant, from:



- a. using the Ozempic<sup>®</sup> and Wegovy<sup>®</sup> marks, including (i) use in any manner that is likely to cause confusion or mistake, to deceive, or otherwise infringe Novo Nordisk's rights in the Ozempic<sup>®</sup> and Wegovy<sup>®</sup> marks, or (ii) use in connection with the advertising, marketing, sale, or promotion of any Unapproved Compounded Drugs; and,
- b. advertising, stating, or suggesting that any Unapproved Compounded Drugs, including any Unapproved Compounded Drugs that either are available, directly or indirectly, from or through Defendant or the use of which or access to which is facilitated by, or with the involvement of, Defendant:
  - i. are, or contain, genuine or authentic Novo Nordisk Ozempic<sup>®</sup> or Wegovy<sup>®</sup> medicines;
  - ii. are sponsored by or associated with Novo Nordisk;
  - iii. are approved by the FDA; have been reviewed by the FDA for safety, effectiveness, or quality; or have been demonstrated to the FDA to be safe or effective for their intended use;
  - iv. achieve or have been shown or proven to achieve certain therapeutic results, effects, or outcomes, including by relying on or making reference to clinical trial results for Novo Nordisk's medicines;
  - v. achieve or have been shown or proven to achieve therapeutic results, effects, or outcomes similar or identical to Novo Nordisk's medicines and/or are interchangeable with or equivalent to genuine Novo Nordisk medicines;

- vi. are associated or connected with Novo Nordisk or Novo Nordisk's medicines; or
  - vii. contain any ingredient (including semaglutide) that is supplied by Novo Nordisk, is approved by the FDA, or is the same as any ingredient in any Novo Nordisk medicine.
- c. engaging in unfair competition with Plaintiffs; and/or
  - d. engaging in deceptive acts or practices.

4. That the Court require Defendant to disclose conspicuously and prominently in any public-facing materials for any Unapproved Compounded Drugs, including all advertising, marketing, and promotional materials, that: (a) the Unapproved Compounded Drugs are compounded drugs that have not been approved by the FDA; have not been reviewed by the FDA for safety, effectiveness, or quality; and have not been demonstrated to the FDA to be safe or effective for their intended use; (b) the processes by which the compounded drugs are manufactured have not been reviewed by the FDA; and (c) FDA-approved medicines containing semaglutide are available.

5. That the Court award Plaintiffs monetary relief in the form of disgorgement of Defendant's profits for Defendant's false advertising and unfair competition and that this monetary relief be trebled due to Defendant's willfulness, in accordance with the provisions of 15 U.S.C. § 1117 and any applicable state laws.

6. That the Court award disgorgement of Defendant's profits resulting from Defendant's infringement of Plaintiffs' rights and by means of Defendant's unfair competition to Plaintiffs.

7. That the Court order Defendant to account for and disgorge to Plaintiffs all amounts by which Defendant has been unjustly enriched by reason of Defendant's unlawful actions.

8. That the Court award Plaintiffs punitive damages by reason of Defendant's willful unlawful actions.

9. That the Court award Plaintiffs pre-judgment and post-judgment interest on all damages.

10. That the Court award Plaintiffs their reasonable attorneys' fees pursuant to 15 U.S.C. § 1117 and any other applicable provision of law.

11. That the Court award Plaintiffs the costs of suit incurred herein.

12. That the Court award such other or further relief as the Court may deem just and proper.

November 8, 2024  
Newark, New Jersey

Respectfully submitted,

s/ Christopher Walsh

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